International Research Policy

1.0 Purpose

The purpose of this policy is to provide guidance on research conducted outside the United States by investigators/employees/students of Georgia Regents University, Georgia Regents Medical Center, or Charlie Norwood VA Medical Center in which the institution, GRU, is engaged. This type of research is considered international research.

2.0 Regulatory Guidance

The Department of Health and Human Services (DHHS) Office for Human Research Protections guidance on international research is located at http://www.hhs.gov/ohrp/international/. This website lists many resources and tools for investigators interested in conducting international research.

Research conducted outside the United States by GRU, GRMC, GR Medical Associates, or CNVAMC investigators falls under the appropriate federal wide assurance (FWA) for each institution.

International research must be submitted and approved by the GRU IRB prior to initiation. The Principal Investigator (PI) is responsible for obtaining approval from the local IRB, ethical oversight committee, or equivalent. If no local IRB or ethical oversight committee exists, the PI is responsible for obtaining approval from local authorities or community leaders to conduct the proposed research.

Department review and approval is required for all international research protocols. This includes initial submissions and amended protocols adding international research sites submitted to the Institutional Review Board (IRB).

For research conducted by VA investigators, a waiver must be obtained by the VA Chief Research and Development Officer prior to submission to the IRB.

Please note that research cannot be approved in countries where an export control or travel embargo are present. The PI should obtain export/embargo information prior to IRB submission.

3.0 Responsibilities of the Principal Investigator Conducting International Research

The PI is responsible for abiding by the rules and regulations set forth by the local IRB as well as GRU IRB. While each culture is respected for its differences, the human participants’ protections must be equally applied and the research must be approved by their local equivalent of an institutional review board. This includes maintaining compliance with the local IRB/ethics committee.
The PI is responsible for ensuring that each research team is familiar with the pertinent laws, regulations and guidelines in the country where their research activities may take place. Some issues that may require additional consideration are:

- Involvement of vulnerable populations
  - Are the US regulations consistent with their idea of vulnerability?
- Informed consent
  - Written versus oral languages
  - English translations and “back” translations
- Local standard of care
  - If a new treatment is offered during the course of the study but not after the study, how does that have an impact on their lives?
- Other issues may be local norms (for example, privacy expectations)

All policies and procedures that are applied to research conducted domestically must be applied to research conducted in other countries, as appropriate.

The PI may be responsible for providing education to the local IRB and should work with the IRB to ensure that communication is as transparent as possible.

All international sites conducting federally funded research must obtain an Assurance for International Institutions. The PI should contact the IRB Office for guidance on this process.

Please contact the IRB Office at IRB@gru.edu for additional guidance.